GMO food safety assessment in China

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Regulations

Law and regulations

Biosafety Office of Agricultural GMOs, MOA
Regulatory regime for risk assessment and management

- Safety Assessment
- Marketing Permit
- Commercial Production Permit
- Processing Permit
- Import Approval
- Product Labeling

Biosafety Office of Agricultural GMOs, MOA
Administrative regulatory system

Joint-Ministerial Conference for Biosafety Management of AgGMOs

MOA, NDRC, MOST, SEPA, MOH, MOC, AQSIQ

MOA

Managing Board for Biosafety of Ag GMOs

Biosafety Office of AgGMOs

Local Agricultural Administrative Departments

Provincial Office for Biosafety Management of AgGMOs

County-level Agricultural Administrative Office

Public Health Administrative Departments

County-level Public Health Administrative Departments

AQSIQ

Institution of Inspection and Quarantine for the Import and Export at Port

MOA, NDRC, MOST, SEPA, MOH, MOC, AQSIQ

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Biosafety Office of Agricultural GMOs, MOA
# Administrative Permit

## Items for Administrative Permit

- Certificate of Approval for AgGMOs
- Biosafety Certificate (for commercialization)
- Certificate of Approval for Importing AgGMOs
- Biosafety Certificate of AgGMOs for foreign R&D company (for Import)
- Biosafety Certificate of AgGMOs for foreign trading company (for Import)
- Certificate of Approval for the Labeling of AgGMOs
- Qualification and authorization for processing AgGMOs
- Approval of AgGMOs imported for direct consumption

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*Biosafety Office of Agricultural GMOs, MOA*
Flow chart of administrative examination and approval for safety assessment of AgGMOs
Safety Assessment

- **Evaluation Principle**: Scientific basis, individual review
- **Evaluation System**:分级管理评价制度
- **Evaluation Categories**: Animal, Plant, Microorganism
- **Evaluation Grades**:
  - I: No existing danger
  - II: Low-level danger
  - III: Medium-level danger
  - IV: High-level danger
- **Evaluation Phases**: Laboratory study, Intermediate trial, Environmental release, Productive trial, Application for safety certificate
- **Reporting System**: Notification
- **Approval System**: Permit

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**Principle of safety assessment**

Biosafety Office of Agricultural GMOs, MOA
## Safety Assessment

### The Status of Approved Safety Assessment during 2002-2005

<table>
<thead>
<tr>
<th>Item</th>
<th>Laboratory study</th>
<th>Restricted field testing</th>
<th>Enlarged field testing</th>
<th>Productive testing</th>
<th>Biosafety certificates</th>
<th>Sub-total</th>
<th>Dis-approved</th>
<th>Total</th>
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<tr>
<td>Plants</td>
<td>1</td>
<td>305</td>
<td>147</td>
<td>143</td>
<td>379</td>
<td>975</td>
<td>232</td>
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<td>Animals</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9</td>
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<td>9</td>
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<tr>
<td>Microorganisms (For plants)</td>
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<td>17</td>
<td>12</td>
<td>5</td>
<td>3</td>
<td>37</td>
<td>7</td>
<td>44</td>
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<tr>
<td>Microorganisms (For animals)</td>
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<td>129</td>
<td>52</td>
<td>33</td>
<td>42</td>
<td>256</td>
<td>9</td>
<td>265</td>
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<tr>
<td>Total</td>
<td>5</td>
<td>456</td>
<td>211</td>
<td>181</td>
<td>424</td>
<td>1277</td>
<td>248</td>
<td>1525</td>
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</tbody>
</table>

Note: 192 domestic and international R&D institutions. Data not including approvals of import GMOs to be used as raw materials for processing.
Safety Assessment

GM vaccine played an important role in preventing bird flu

GM rice, oilseed rape with high oil content and papaya approved for productive testing

GM tomato, sweet pepper, chilli pepper and petunia were granted safety certificates for commercial production

A total of 3.4 million hectares of Bt cotton were planted in China in 2005

Biosafety Office of Agricultural GMOs, MOA
Safety Assessment

Safety Control Measures: physical, chemical, biological, scale controls

Genetic Stability: indoor and outdoor testing

Food Safety Assessment: nutrition, toxicity, allergenicity, unintended effects

Environmental Safety Assessment: survival and competitiveness, gene flow, non-target effects and biodiversity, unintended effect

Safety Control Measures: physical, chemical, biological, scale controls

1. Laboratory study
2. Restricted field testing
3. Enlarged field testing
4. Productive testing
5. Application for safety certificate

Biosafety Office of Agricultural GMOs, MOA
AgGMOs listed in the labeling catalogue shall be clearly labeled when they are sold in the territories of the P.R. China. Any companies, organizations or individuals engaged in producing or dealing imported AgGMOs are required to get permit from local agricultural administrative office above county level. Provincial agricultural administrative departments should report to MOA.
Product labeling

First category of labeling list of AgGMOs and its products

- Soybean seeds, soybean, soybean flour, soybean oil, soybean meal
- Maize seeds, maize, maize oil, maize flour
- Oilseed rape seeds, oilseed rape grain, oil made from oilseed rape, oilseed rape meal
- Cotton seeds
- Tomato seeds, fresh tomato, tomato sauce

Labeling in the processing unit

Biosafety Office of Agricultural GMOs, MOA
Import Approval

- Imported or introduced AgGMOs are subjected to safety assessment according to their intended uses:
  - for research and testing
  - for commercial production
  - as raw materials for processing

Flow chart of safety assessment and approval for import as raw materials for processing

Biosafety Office of Agricultural GMOs, MOA
Import approval

<table>
<thead>
<tr>
<th>审批编号</th>
<th>转基因生物</th>
<th>研发单位</th>
<th>性  状</th>
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<tr>
<td>农基安证字(2004)第002号</td>
<td>转基因大豆GTS40-3-2</td>
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<td>转基因玉米NK603</td>
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</tbody>
</table>

A list of safety certificates of AgGMOs for import as raw materials for processing

Biosafety Office of Agricultural GMOs, MOA
Import – risk assessment requirement

Environmental and food safety testing of AgGMOs for import as raw materials for processing

Field testing of an insect-resistant GM maize, Mon 810 in Shandong Province

Field testing of a herbicide-tolerant GM soybean in Hebei Province

Animal test at China CDC by feeding experimental piggy with herbicide-tolerant maize NK 603 developed by Monsanto

Animal test at a MOA laboratory by feeding experimental rats with Bt 176, a GM maize developed by Syngenta

Biosafety Office of Agricultural GMOs, MOA
Any organizations or individuals engaged in processing AgGMOs within China are required to get permit for processing AgGMOs from provincial agricultural administrative office.

MOA Biosafety Office and Qingdao Agricultural Bureau inspecting the safety control of the firm conducting AgGMOs processing.
Communication and Training

Trained 29087 personnel, granted 8336 law enforcement certificates

More than 40 members from the National Technical Committee for Standardization of Safety Management of AgGMOs participated in a standardization workshop

About 90 participants from 30 organizations were trained in training courses for GM cotton detection in 2005

Over 400 participants attended safety assessment training courses

Biosafety Office of Agricultural GMOs, MOA
Technical System

Technical support system for safety regulation of AgGMOs

Safety Assessment
- National Biosafety Committee
  - Responsible for safety assessment of AgGMOs
  - Group for plants & microorganisms used in plants
  - Group for animals & microorganisms used in animals
  - Group for food and feed safety

Technical Standards
- National Technical Committee for Standardization of Safety Management of AgGMOs
  - In charge of drafting and revision of technical standards for biosafety of AgGMOs
  - Basic Standards
  - St. for Safety Assessment
  - St. for Testing and Detection
  - St. for Safety Management

Technical Testing
- Environmental Safety Testing
- Food Safety Testing
- GMO Detection
  - 49 centers for supervision, inspection and testing of AgGMOs were established

Monitoring
- Integrated
- Regional
- Specific
- Plants
- Animals
- Microorganisms

Non-GM soybean monitoring area in the North East
Biodiversity conservation area in Hainan
Cotton planting area in Xinjiang
Cotton planting area in Yellow River area
Cotton planting area along mid- and down-stream of Yangtse River
Coastal area for processing AgGMOs

Biosafety Office of Agricultural GMOs, MOA
Technical System

- Biosafety Assessment System

The National Biosafety Committee of AgGMOs consists of 64 experts from 9 ministries, 9 research institutions and 9 universities with multidisciplinary background.
Technical System

- Standardization System

National Technical Committee for standardization of Biosafety Management of AgGMOs consists of 41 experts and administrative officials. Published 12 standards

Biosafety Office of Agricultural GMOs, MOA
Technical System

Technical Testing System

Isolated field trials of GM rice

PCR analysis

Field performance testing of a GM rice line for its resistance to insect pests

Biosafety Office of Agricultural GMOs, MOA
Technical System

- Biosafety Monitoring System

Processing Area

Environmental Impact Area

Biosafety Office of Agricultural GMOs, MOA
Supervision and Inspection

Guidelines for field trial safety inspection

Foundation for Inspection
- Related requirements from the Regulations
- Safety assessment documents granted by MOA

Inspection Preparation
- Targets of Inspection: restricted field testing, enlarged field testing and productive testing
- Inspection Time: at sowing, pre-blooming, at harvesting and after experimentation
- Inspection Personnel: County agricultural administrative office is responsible for routine inspection; Provincial agricultural department is responsible for supervision and spot-checking at key period
- Inspection Planning: preparing relevant documents and training inspection personnel

Substance of Inspection
- At sowing: Experimental materials and test area, measures for safety control and measures for handling left materials
- Pre-blooming: Data records, isolation measures, testing size, etc.
- At harvesting: Measures of harvesting, storing, handling and destroying plant residues
- After experiment: Measures for the removal of volunteer plants and residues

Inspection Methods
- Self inspection of R&D organization jointed with enforced inspection
- R&D organization should fill in the self inspection form according to the facts
- Local law enforcement officials should carry out spot check, fill in inspection form, put forward suggestions and report to superior agricultural administrative office
- Provincial agricultural administrative office should gather all inspection reports and report to the MOA

Deal with Relevant Issues
- Give suggestion on the spot and supervise the correction
- Terminate the experiment and yield punishment
- For those with disagreement or with possible incidence, the MOA shall entrust technical inspection body to collect and authenticate samples and handle the incidence

Biosafety Office of Agricultural GMOs, MOA
Supervision and Inspection

- Mr. Zhang Baowen, vice minister of MOA addressed in the national meetings on supervision and inspection

- Law enforcement officials inspecting a field trial of GM wheat in Hebei

Biosafety Office of Agricultural GMOs, MOA
Supervision and Inspection

- Following the examination and approval measures for processing and getting ready

Law enforcement officials inspecting agricultural GM product labeling in Beijing

Law enforcement officials inspecting GM cotton market in Shandong

Biosafety Office of Agricultural GMOs, MOA
International Cooperation & Exchange

- Chinese delegate attending the APEC high level policy dialogue on agricultural biotechnology
- Sino-Canada Workshop on GMO Regulation
- EU-China Symposium on Agricultural Biotechnology
- Chinese delegate visiting Japan
- Visiting the Japanese Institute of Agricultural Bioresources
- Sino-Canada Workshop on GMO Regulation

Biosafety Office of Agricultural GMOs, MOA
Public Communication

- MOA press conference announcing testing result on the Heinz infant rice flour products
- Beijing Agricultural Bureau explains the GMO regulations
- Professor Wu Kong-ming, the Director of IPP, CAAS, answers GMO safety questions
- Questions and Answers on GMO regulations

*Biosafety Office of Agricultural GMOs, MOA*
GM rice for insect resistance

GM rice lines with cry1Ab gene for insect resistance have been approved for field testing. Field trials showed that the Bt rice had little effect on non-target organisms and arthropod communities in Bt rice paddies in the field.

- A field trial of Bt rice for insect resistance evaluation
- Newly hatched *Chilo suppressalis* larva were killed on Bt rice
- Field testing of Bt rice for environmental impact

*Biosafety Office of Agricultural GMOs, MOA*
GM plants
(Peking University)

- *Petunia hybrida*, genetically modified with chalcone synthase-A (CHSA). Red flower is from non-GM plant, white and bi-colored flowers are from GM plants.

- Virus-resistant tomato genetically modified with CMV-CP

- Virus-resistant sweet pepper genetically modified with CMV-CP
GM papaya
(South China Agricultural University)

Huanong 1, GM papaya with replicase gene of papaya ringspot virus (PRSV), demonstrating high quality and virus resistance

Symptom in papaya showing PRSV infection

Field trials of GM papaya

Flow chart showing the procedures of propagating Huanong 1 in factory

Huanong 1, GM papaya, showing high quality and resistance

Biosafety Office of Agricultural GMOs, MOA
GM cotton for insect resistance
(Biotechnology Research Institute, CAAS)

GM cotton varieties for insect resistance with modified Cry1A and CpTI genes approved for commercial cultivation

Greenhouse testing

Bioassay

Commercial cultivation of GM cotton

Biosafety Office of Agricultural GMOs, MOA
Lines of GM fish with gene(s) from another fish for fast growth have been approved for field testing, including a GM triploid carp line.
Transgenic cattle have been obtained with either human lysozyme (hLY) gene or human fucosylated sugar transferase gene expression. Transgenic cloning cattle with human lactoferrin cDNA (hLF) gene expression have also succeeded.
Transgenic goat with human lactoferrin gene is granted for enlarged field testing. Transgenic goat with human lysozyme gene is in the restricted field testing.

Testing the performance of hLY. Left: result of 5 min after adding hLY; Right: CK

Transgenic goat with hLF gene: expressed 0.7 g/L hLF

Transgenic goat with hLY gene: expressed 2.5 g/L hLY

Pure human lactoferrin and human lysozyme isolated from transgenic female goat with hLF cDNA, transgenic female goat with hLY gene
Safe use of Modern Biotechnology such as GMOs, will contribute to global food safety and food security.
Thank you